

# EXHIBIT

## 16

**From:** "Zimmerman, Chris" <CZimmerman@amerisourcebergen.com>  
**Sent:** Mon, 9 Jul 2012 08:57:47 -0400 (EDT)  
**To:** "Breitmayer, David" <DBreitmayer@amerisourcebergen.com>, "Cherveny, Eric" <ECherveny@amerisourcebergen.com>, "Crow, Robert" <RCrow@amerisourcebergen.com>, "Droz, Antonio" <ADroz@amerisourcebergen.com>, "Flood, Clifford" <CFlood@amerisourcebergen.com>, "Frost, Nicole" <NFrost@amerisourcebergen.com>, "Garcia, Elizabeth" <EGarcia@amerisourcebergen.com>, "Glover, Sherrice" <SGlover@amerisourcebergen.com>, "Gundy, Bruce" <BGundy@amerisourcebergen.com>, "Hazewski, Edward" <EHazewski@amerisourcebergen.com>, "Kreutzer, Kevin" <KKreutzer@amerisourcebergen.com>, "Madsen, Greg" <GMadsen@amerisourcebergen.com>, "Marcum, Cathy" <CMarcum@amerisourcebergen.com>, "Mays, Steve" <SMays@amerisourcebergen.com>, "Ross, Paul" <PRoss@amerisourcebergen.com>, "Tomkiewicz, Joseph" <JTomkiewicz@amerisourcebergen.com>  
**Subject:** FW: First News: Monday, July 9, 2012 PC Version



## First News: Monday, July 9, 2012

**Report Overview:**  
**Total Clips (11)**  
**Current Issues (7)**  
**Generics (1)**  
**Industry (1)**  
**Retail Strategic Accts (2)**

Headline	Date	Outlet	Links
----------	------	--------	-------

### Current Issues (7)

	<b>States Interpret Ruling to Cut Medicaid Now</b>	07/09/2012	Wall Street Journal	<a href="#">Text</a>	<a href="#">View Clip</a>
	<b>NYT: Long shot against leukemia yields cancer culprit</b>	07/09/2012	New York Times, The	<a href="#">Text</a>	<a href="#">View Clip</a>
	<b>A New Treatment's Tantalizing Promise Brings Heartbreaking Ups and Downs</b>	07/09/2012	New York Times, The	<a href="#">Text</a>	<a href="#">View Clip</a>
	<b>States fight 'tourists' trafficking painkillers</b>	07/08/2012	Macomb Daily	<a href="#">Text</a>	<a href="#">View</a>

	<b>Workplace clinics gaining favor among employers</b>	07/08/2012	<i>Chicago Tribune - Online</i>	<a href="#">Text</a>	<a href="#">View Clip</a>
	<b>Canada: Province boosts pharmacists' compensation</b>	07/07/2012	<i>St. Albert &amp; Sturgeon Gazette - Online</i>	<a href="#">Text</a>	<a href="#">View Clip</a>
	<b>Half of all heart patients make medication errors</b>	07/07/2012	<i>MSNBC.com</i>	<a href="#">Text</a>	<a href="#">View Clip</a>
<hr/>					
<b>Generics (1)</b>					
	<b>Canada: Ont Health Minister moves to block generic OxyContin</b>	07/07/2012	<i>CFRB-AM - Online</i>	<a href="#">Text</a>	<a href="#">View Clip</a>
<hr/>					
<b>Industry (1)</b>					
	<b>After Delay, OxyContin's Use in Young Under Study</b>	07/07/2012	<i>New York Times, The</i>	<a href="#">Text</a>	<a href="#">View Clip</a>
<hr/>					
<b>Retail Strategic Accts (2)</b>					
	<b>Express Scripts, Walgreen Flap Opens Door for 'Narrow Networks'</b>	07/09/2012	<i>Dow Jones Newswires</i>	<a href="#">Text</a>	<a href="#">View Clip</a>
	<b>Delaware: Return of the independent druggist</b>	07/08/2012	<i>News Journal - Online</i>	<a href="#">Text</a>	<a href="#">View Clip</a>

**States Interpret Ruling to Cut Medicaid Now | [View Clip](#)**  
**07/09/2012**  
**Wall Street Journal**

Some cash-strapped states have seized on a section of the Supreme Court's health-law decision to pare their existing Medicaid programs, saying the ruling lifts the March 2010 law's ban on such cuts.

The court, which upheld most of the law, struck down penalties for states choosing not to expand Medicaid. A few states are also trying to go farther, arguing that the ruling justifies cuts to their existing programs.

**Earlier**  
**Some States Balk at Medicaid Expansion**

Within hours of the Supreme Court's ruling on June 28, lawyers in the Maine attorney general's office began preparing a legal argument to allow health officials to strike more than 20,000 Medicaid recipients from the state's rolls—including 19- and 20-year-olds—beginning in October to save \$10 million by next July.

"We think we're on solid legal ground," Attorney General William Schneider said in an interview. "We're going to reduce eligibility back to the base levels in a couple of areas," he said. Maine, like some other states eyeing cuts, earlier expanded its Medicaid program

beyond national requirements.

Other states, including Wisconsin and Alabama, are expected to follow Maine's lead, though there is disagreement over whether the high court gave the states such leeway. That could lead to battles between states and the federal government that could drag the health law back to the courts. New Jersey and Indiana also said they were evaluating the decision and did not rule out challenging the requirements.

The federal Department of Health and Human Services is still examining the court's ruling and its implications for eligibility rules, an official said.

Last week's Supreme Court decision, written by Chief Justice John Roberts, largely upheld the federal health law, but said Washington couldn't penalize states that refuse to enroll millions more low-income people in their Medicaid programs by withdrawing support for their existing programs; the expansion effort is supposed to start in 2014 with a large injection of federal financing.

Some states are now asserting they have more flexibility to manage other aspects of the program. The law had required states to keep their existing eligibility standards for current beneficiaries in place or risk losing federal funding at least until 2014. Some state officials said the Supreme Court ruling nixed that penalty, too.

The federal government currently contributes around 57% of the financing for Medicaid programs carried out by the states, and sets restrictions on how states use the money.

States facing budget crunches have been trying to limit Medicaid eligibility for the last year and a half, but had little sympathy from Washington. Health Secretary Kathleen Sebelius told governors in February 2011 that they should look for cuts elsewhere, such as cutting back on benefits. "This has a game changing potential that goes beyond what people think is just a simple straightforward question about Medicaid expansion," said Dennis Smith, Wisconsin's health secretary. "States are scrambling to see how far they can stretch it."

Wisconsin recently sought to remove 60,000 people, including children, from its Medicaid rolls, but federal officials denied the move. The two sides ultimately reached a deal to strip 17,000 Medicaid beneficiaries.

"I think the logic of the Roberts decision would reopen the matter," said Mr. Smith, who was the top federal Medicaid official during the George W. Bush administration.

Don Williamson, Alabama state health officer, said officials are looking at restricting eligibility for Alabama's children's health insurance program for the fiscal year starting Oct. 1 if federal officials officially lift the ban on changing eligibility. The move is aimed at closing a \$15 million funding gap for the program, he said.

Some experts said the court decision didn't clearly give a green light to states that want to change eligibility requirements.

"The court decision was not crystal clear," said Alan Weil, a former Medicaid director and head of the nonpartisan National Academy for State Health Policy. "I've been telling people [the rules] are still there." Still, he said he expects some states will challenge the federal government.

Maine could be the first to test the question. The state had initially planned to ask federal

Medicaid officials to waive the rules so they could cut their Medicaid rolls, an action the state legislature approved in May. Maine officials now believe they can make the changes on their own.

The state Medicaid agency is preparing to officially file its changes with the federal government in two or three weeks, said John Martins, a Maine Department of Health and Human Services spokesman. Federal officials could still try to block it, which could trigger a new court battle.

[Return to Top](#)

---

**NYT: Long shot against leukemia yields cancer culprit | [View Clip](#)**  
**07/09/2012**  
***New York Times, The***

ST. LOUIS — Genetics researchers at Washington University , one of the world's leading centers for work on the human genome, were devastated. Dr. Lukas Wartman, a young, talented and beloved colleague, had the very cancer he had devoted his career to studying. He was deteriorating fast. No known treatment could save him. And no one, to their knowledge, had ever investigated the complete genetic makeup of a cancer like his.

So one day last July, Dr. Timothy Ley, associate director of the university's genome institute, summoned his team. Why not throw everything we have at seeing if we can find a rogue gene spurring Dr. Wartman's cancer, adult acute lymphoblastic leukemia, he asked? "It's now or never," he recalled telling them. "We will only get one shot."

Dr. Ley's team tried a type of analysis that they had never done before. They fully sequenced the genes of both his cancer cells and healthy cells for comparison, and at the same time analyzed his RNA, a close chemical cousin to DNA, for clues to what his genes were doing.

The researchers on the project put other work aside for weeks, running one of the university's 26 sequencing machines and supercomputer around the clock. And they found a culprit — a normal gene that was in overdrive, churning out huge amounts of a protein that appeared to be spurring the cancer's growth.

Even better, there was a promising new drug that might shut down the malfunctioning gene — a drug that had been tested and approved only for advanced kidney cancer . Dr. Wartman became the first person ever to take it for leukemia.

And now, against all odds, his cancer is in remission and has been since last fall.

While no one can say that Dr. Wartman is cured, after facing certain death last fall, he is alive and doing well. Dr. Wartman is a pioneer in a new approach to stopping cancer. What is important, medical researchers say, is the genes that drive a cancer, not the tissue or organ — liver or brain, bone marrow, blood or colon — where the cancer originates.

One woman's breast cancer may have different genetic drivers from another woman's and, in fact, may have more in common with prostate cancer in a man or another patient's lung cancer.

Under this new approach, researchers expect that treatment will be tailored to an individual tumor 's mutations, with drugs, eventually, that hit several key aberrant genes at once. The

cocktails of medicines would be analogous to H.I.V. treatment, which uses several different drugs at once to strike the virus in a number of critical areas.

Researchers differ about how soon the method, known as whole genome sequencing, will be generally available and paid for by insurance — estimates range from a few years to a decade or so. But they believe that it has enormous promise, though it has not yet cured anyone.

With a steep drop in the costs of sequencing and an explosion of research on genes, medical experts expect that genetic analyses of cancers will become routine. Just as pathologists do blood cultures to decide which antibiotics will stop a patient's bacterial infection, so will genome sequencing determine which drugs might stop a cancer.

"Until you know what is driving a patient's cancer, you really don't have any chance of getting it right," Dr. Ley said. "For the past 40 years, we have been sending generals into battle without a map of the battlefield. What we are doing now is building the map."

Large drug companies and small biotechs are jumping in, starting to test drugs that attack a gene rather than a tumor type.

Leading cancer researchers are starting companies to find genes that might be causing an individual's cancer to grow, to analyze genetic data and to find and test new drugs directed against these genetic targets. Leading venture capital firms are involved.

For now, whole genome sequencing is in its infancy and dauntingly complex. The gene sequences are only the start — they come in billions of small pieces, like a huge jigsaw puzzle. The arduous job is to figure out which mutations are important, a task that requires skill, experience and instincts.

So far, most who have chosen this path are wealthy and well connected. When Steve Jobs had exhausted other options to combat pancreatic cancer, he consulted doctors who coordinated his genetic sequencing and analysis. It cost him \$100,000, according to his biographer. The writer Christopher Hitchens went to the head of the National Institutes of Health, Dr. Francis Collins, who advised him on where to get a genetic analysis of his esophageal cancer.

Harvard Medical School expects eventually to offer whole genome sequencing to help cancer patients identify treatments, said Heidi L. Rehm, who heads the molecular medicine laboratory at Harvard's Partners Healthcare Center for Personalized Genetic Medicine. But later this year, Partners will take a more modest step, offering whole genome sequencing to patients with a suspected hereditary disorder in hopes of identifying mutations that might be causing the disease.

Whole genome sequencing of the type that Dr. Wartman had, Dr. Rehm added, "is a whole other level of complexity."

Dr. Wartman was included by his colleagues in a research study, and his genetic analysis was paid for by the university and research grants. Such opportunities are not available to most patients, but Dr. Ley noted that the group had done such an analysis for another patient the year before and that no patients were being neglected because of the urgent work to figure out Dr. Wartman's cancer.

"The precedent for moving quickly on a sample to make a key decision was already established," Dr. Ley said.

Ethicists ask whether those with money and connections should have options far out of reach for most patients before such treatments become a normal part of medicine. And will people of more limited means be tempted to bankrupt their families in pursuit of a cure at the far edges?

"If we say we need research because this is a new idea, then why is it that rich people can even access it?" asked Wylie Burke, professor and chairwoman of the department of bioethics at the University of Washington. The saving grace, she said, is that the method will become available to all if it works.

#### A Life in Medicine

It was pure happenstance that landed Dr. Wartman in a university at the forefront of cancer research. He grew up in small-town Indiana, aspiring to be a veterinarian like his grandfather. But in college, he worked summers in hospitals and became fascinated by cancer. He enrolled in medical school at Washington University in St. Louis, where he was drawn to research on genetic changes that occur in cancers of the blood. Dr. Wartman knew then what he wanted to do — become a physician researcher.

Those plans fell apart in the winter of 2002, his last year of medical school, when he went to California to be interviewed for a residency program at Stanford. On the morning of his visit, he was nearly paralyzed by an overwhelming fatigue.

"I could not get out of bed for an interview that was the most important of my life," Dr. Wartman recalled. Somehow, he forced himself to drive to Palo Alto in a drenching rain. He rallied enough to get through the day.

When he returned to St. Louis, he gave up running, too exhausted for the sport he loved. He started having night sweats.

"I thought it might be mono," he said. "And I thought I would ride it out."

But then the long bones in his legs began to hurt. He was having fevers.

He was so young then — only 25 — and had always been so healthy that his only doctor was a pediatrician. So he went to an urgent care center in February 2003. The doctor there thought his symptoms might come from depression, but noticed that his red and white blood cell counts were low. And Lukas Wartman, who had been fascinated by the biology of leukemia, began to suspect he had it.

"I was definitely scared," he said. "It was so unreal."

The next day, Mr. Wartman, who was about to graduate from Washington University's medical school, went back there for more tests. A doctor slid a long needle into his hip bone and drew out marrow for analysis.

"We looked at the slide together," Dr. Wartman said, recalling that terrible time. "It was packed with leukemia cells. I was in a state of shock."

Dr. Wartman remained at the university for his residency and treatment: nine months of intensive chemotherapy, followed by 15 months of maintenance chemotherapy. Five years passed when the cancer seemed to be gone. But then it came back. Next came the most risky remedy — intensive chemotherapy to put the cancer into remission followed by a bone-

marrow transplant from his younger brother.

Seven months after the transplant, feeling much stronger, he went to a major cancer meeting and sat in on a session on his type of leukemia. The speaker, a renowned researcher, reported that only 4 or 5 percent of those who relapsed survived.

"My stomach turned," Dr. Wartman said. "I will never forget the shock of hearing that number."

But his personal gauge of recovery — how far he could run — was encouraging.

By last spring, three years after his transplant, Dr. Wartman was running six to seven miles every other day and feeling good. "I thought maybe I would run a half marathon in the fall."

Then the cancer came back. He remembered that number, 4 or 5 percent, for patients with one relapse. He had relapsed a second time.

This time, he said, "There is no number."

His doctors put him on a clinical trial to try to beat the cancer with chemotherapy and hormones. It did not work.

They infused him with his brother's healthy marrow cells, to no avail.

#### A Clue in RNA

Dr. Wartman's doctors realized then that their last best hope for saving him was to use all the genetic know-how and technology at their disposal.

After their month of frantic work to beat cancer's relentless clock, the group, led by Richard Wilson and Elaine Mardis, directors of the university's genome institute, had the data. It was Aug. 31.

The cancer's DNA had, as expected, many mutations, but there was nothing to be done about them. There were no drugs to attack them.

But the other analysis, of the cancer's RNA, was different. There was something there, something unexpected.

The RNA sequencing showed that a normal gene, FLT3, was wildly active in the leukemia cells. Its normal role is to make cells grow and proliferate. An overactive FLT3 gene might be making Dr. Wartman's cancer cells multiply so quickly.

Even better, there was a drug, sunitinib or Sutent, approved for treating advanced kidney cancer, that inhibits FLT3.

But it costs \$330 a day, and Dr. Wartman's insurance company would not pay for it. He appealed twice to his insurer and lost both times.

He also pleaded with the drug's maker, Pfizer, to give him the drug under its compassionate use program, explaining that his entire salary was only enough to pay for 7 ½ months of Sutent. But Pfizer turned him down too.



As September went by, Dr. Wartman was getting panicky.

"Every day is a roller coaster," he said at the time, "and everything is up in the air."

Desperate to try the drug, he scraped up the money to buy a week's worth and began taking it on Sept. 16. Within days, his blood counts were looking more normal.

But over dinner at a trendy St. Louis restaurant, he picked at his chicken and said he was afraid to hope.

"Obviously it's exciting," he said. "But Sutent could have unanticipated effects on my bone marrow." Maybe his rising red blood cell counts were just a side effect of the drug. Or maybe they were just a coincidence.

"It's hard to say if I feel any different," Dr. Wartman said.

And the cost of the drug nagged at him. If it worked, how long could he afford to keep taking it?

The next day, a nurse at the hospital pharmacy called with what seemed miraculous news: a month's supply of Sutent was waiting for Dr. Wartman. He did not know at the time, but the doctors in his division had pitched in to buy the drug.

Two weeks later, his bone marrow, which had been full of leukemia cells, was clean, a biopsy showed.

Still, he was nervous. The test involved taking out just a small amount of marrow. Cancer cells could be lurking unseen.

The next test was flow cytometry, which used antibodies to label cancer cells. Again, there were no cancer cells.

But even flow cytometry could be misleading, Dr. Wartman told himself.

Finally, a yet more sensitive test, called FISH, was done. It labels cancer cells with fluorescent pieces of DNA to identify leukemia cells. Once again, there were none.

"I can't believe it," his awe-struck physician, Dr. John DiPersio, told him.

Dr. Wartman, alone in his apartment, waited for his partner, Damon Berardi, to come home from work. That evening, Mr. Berardi, a 31-year-old store manager, opened the door with no idea of Dr. Wartman's momentous news. To his surprise, Dr. Wartman was home early, waiting in the kitchen with champagne and two flutes he had given Mr. Berardi for Christmas. He told Mr. Berardi he should sit down.

"My leukemia is in remission," he said. The men embraced exultantly, and Dr. Wartman popped open the champagne.

"I felt an overwhelming sense of relief and a renewed vision of our future together," Mr. Berardi said. "There were no tears at that moment. We had both had cried plenty. This was a moment of hope."

## Hunches and Decisions

Dr. Wartman and his doctors had fateful decisions to make, with nothing but hunches to guide them. Should he keep taking Sutent or have another bone-marrow transplant now that he was in remission again?

In the end, Dr. DiPersio decided Dr. Wartman should have the transplant because without it the cancer might mutate and escape the Sutent.

Meanwhile, Pfizer had decided to give him the drug. Dr. Wartman has no idea why. Perhaps the company was swayed by an impassioned plea from his nurse practitioner, Stephanie Bauer.

Dr. Wartman's cancer is still gone, for now, but he has struggled with a common complication of bone-marrow transplants, in which the white blood cells of the transplanted marrow attack his cells as though they were foreign. He has had rashes and felt ill. But these complications are gradually lessening, and he is back at work in Dr. Ley's lab.

His colleagues want to look for the same mutation in the cancer cells of other patients with his cancer. And they would like to start a clinical trial testing Sutent to discover whether the drug can help others with leukemia, or whether the solution they found was unique to Lukas Wartman.

Dr. Wartman himself is left with nagging uncertainties. He knows how lucky he is, but what does the future hold? Can he plan a life? Is he cured?

"It's a hard feeling to describe," he said. "I am in uncharted waters."

This article, "Genetic gamble: In treatment for leukemia, glimpses of the future," first appeared in The New York Times.

Copyright © 2012 The New York Times

Show more text

Jump to text

ST. LOUIS — Genetics researchers at , one of th...

Jump to discussion

NYT: To save one of their own, cancer researcher...

Jump to related

Cancer

[Return to Top](#)

---

**A New Treatment's Tantalizing Promise Brings Heartbreaking Ups and Downs | [View Clip](#)**

07/09/2012  
*New York Times, The*

Beth McDaniel's oncologist, a bear of a man, hugged her and twirled her around.

"Holy cow, Beth!" Dr. John J. Gohmann exclaimed.

For the first time since a rare cancer appeared eight years before, her lymph nodes had shrunk to a normal size, her skin was no longer bright red and inflamed, and the itchiness that plagued her had subsided.

Mrs. McDaniel, the 69-year-old wife of a retired corporate executive, had gambled on the ultimate in personalized medicine, an approach known as whole genome sequencing, and it seemed to be paying off.

Scientists had compared the entire genetic sequences of the tumor cells invading her body with those in her healthy cells, searching for mutated tumor genes that could be thwarted by drugs approved for other cancers or even other diseases. That had led them to give her an expensive drug approved just a month earlier for melanoma patients. It had never been given to anyone with a blood cell cancer like hers. In theory, the drug should have killed her. Instead, it seemed to have halted or even reversed her cancer.

But would it last? And what would it mean if it did not?

In the end, Mrs. McDaniel's journey to the edge of genetics research turned out to be a decidedly mixed experience. It was hard — much harder than anyone in her family had imagined — to get the sequencing and analysis done. It was breathtaking to see the results, which indicated that her cancer was driven by a strange gene aberration that could be attacked with a new drug. But it was heartbreaking to see how quickly her cancer recovered from the assault, roaring back in a matter of weeks.

Mrs. McDaniel's story offers a sobering look at the challenges for this kind of quest for a treatment, even for someone like her, who had both the means and the connections to get the intricate geography of her cancer charted. Her husband, Roger McDaniel, was a former chief executive of two companies involved in semiconductor manufacturing, and the family could afford the approximately \$49,000 that the search would cost. They had expected to pay much more, but to their astonishment, Mrs. McDaniel's insurance company covered almost all the drug costs. And the scientists who did the data analysis did not charge.

From the start, the family knew the odds were against Mrs. McDaniel, but she thought she had little to lose.

"You cannot feel bad if this doesn't work or I die," she told her son Timothy, a molecular biologist. "I would have died anyway."

#### Scarlet Skin and Infections

Beth McDaniel's cancer began with itching all over her body. Then her skin turned scarlet and started becoming infected.

In 2005, after she had spent more than a year going from specialist to specialist, a dermatologist figured it out. Mrs. McDaniel, then 62, had Sezary syndrome, a rare T cell lymphoma, in which white blood cells become cancerous and migrate to the skin. All her

doctors could tell her was that the disease was incurable, that there was no standard treatment, and that on average patients at her stage die within a few years.

"Of course I was shocked," Mrs. McDaniel said in an interview last September.

She wept that day as her husband drove her home. And she asked God to help her cope.

Before cancer, she had had a vibrant life, hiking in the mountains, traveling the world, entertaining her wide network of friends. Her disease destroyed all of that. She could not even enjoy her luxuriant garden because sun on her inflamed skin was agony.

Although there is no standard treatment, for five years chemotherapy held her disease at bay. But in the summer of 2010, she got worse, much worse, with hundreds of tumors popping up under her skin. Some grew as large as kiwi fruits and split open.

Her son, Dr. McDaniel, decided he would orchestrate the use of the most advanced techniques of gene sequencing and analysis to take on her cancer. Because of his job — he works for Illumina, a company that does DNA sequencing — Dr. McDaniel had read scientific reports and gone to medical conferences where he heard talks on whole genome sequencing. He noticed that the patients all seemed to have rare cancers.

"Every time I heard one of those stories, I thought, 'That's my mom,' " he said.

For now, there are not many drugs that can target specific gene mutations in cancer cells.

But the hope is that when more is known and more drugs are developed, doctors will treat cancer by blocking several major genes at once. With several escape routes barred, the cancer will not be able to break free of the drugs stopping its growth.

#### Full-Time Help From a Son

In theory, it seemed straightforward for Dr. McDaniel to help his mother. The technology for getting and analyzing DNA sequences has advanced greatly, and the cost has plummeted. In fact, Dr. McDaniel said, the price of sequencing has dropped so fast that if the work were done today, it would cost just \$26,200 instead of the \$46,280 it cost last year.

The first obstacle was just getting a sample of Mrs. McDaniel's cancer cells. One doctor told her the odds of success were so slim that she would be better off spending her money on a vacation. Another seemed interested but did not follow through. A third did two biopsies but was unable to get usable DNA.

Finally, Dr. McDaniel and his wife, Gia, decided he would make helping his mother a full-time job. He took a leave of absence from Illumina, and he, Gia and their three young children moved from San Diego to Lexington, Ky.

"I have not been a particularly humble person," Beth McDaniel said. "That humbled me."

Dr. McDaniel's parents had two homes in the Lexington area. One, on a horse farm, was vacant, and he appropriated a bedroom on the second floor for his office. He treated his work like a regular job, driving to the office each day from another house where he and his family were living. He dressed in his normal work clothes, slacks and a collared shirt. Meanwhile, his mother's cancer was erupting.

"She was covered in tumors, almost like cobblestones," said Dr. Fernando R. de Castro, her dermatologist. "They felt like marbles and pebbles all over her skin." Large ones on her arms and legs had burst open. "We started talking about hospice."

Mrs. McDaniel said she was not a vain person, but with red lumps all over her face, she was embarrassed to go out. She slept on a cooling pad and carried one with her to relieve the constant itching.

Every evening around 5:30 when the itching became most unbearable, she would lay her head in her husband's lap as they watched TV in their great room and he would gently tickle her back for hours on end — trying to ease her discomfort.

The disease continued a relentless course until finally, accepting what seemed the inevitable, Mrs. McDaniel gave away her clothes, planned her funeral and wrote notes to a few people she thought she had offended in her life, asking them to forgive her.

"She believed, we all believed, she would die before we got the sequencing done," Dr. McDaniel said.

Then, in January 2011, Dr. de Castro got a tissue sample from a tumor and, for comparison with normal cells, her saliva. He had removed a plug of tissue the size of a pencil eraser from one of the hundreds of tumors on Mrs. McDaniel's skin, frozen it in liquid nitrogen and shipped it overnight to the Mayo Clinic in Scottsdale, Ariz. By April, scientists at Illumina and TGen, a nonprofit research institute, had completed the genetic sequencing of the samples.

Next came the hard part — the analysis. With time short, Dr. McDaniel worked on it himself and recruited two small biotechnology companies and TGen to help.

#### Three Billion Symbols in a Cell

John Carpten, an oncologist at TGen, and David Craig are accustomed to working with gene sequence data, but it is hard even for them to get used to the scale of such a project.

The hard drive containing Mrs. McDaniel's genetic data arrived in the mail — it had too much data to send electronically. It took a full day just to pull this terabyte of information off the drive. Dr. Carpten explained that there were three billion symbols, made from four letters — A, T, G and C — in just one cell's DNA. If those letters were printed on paper, they would fill a medium-sized elementary school's library.

But there are unavoidable errors in sequencing, so to be sure the data is correct, researchers repeat the sequencing 30 times — 30 libraries' worth. They do this for the normal cells, too — another 30 libraries' worth. This kind of data, though, does not come in neat genetic words and sentences. Instead, Dr. Craig said, "It looks like it's been through a shredder."

"It is like putting together a jigsaw puzzle that has a billion pieces," Dr. Carpten said.

Finally, they compared the sequences of normal cells and cancer cells. They found about 18,000 differences, most with no known significance for the disease.

At last, the work was done, and on May 18, Dr. McDaniel flew to TGen. The researchers noticed an intriguing aberration in Mrs. McDaniel's cancer genes. But they were uncertain what it meant.

It looked as if two genes had fused to each other in Mrs. McDaniel's cancer cells. The result was that the cell growth signals in the cancer cells were reversed, like crossed wires. The research team theorized that every time those cancer cells, T cells of her immune system, got a signal to stop growing, they reacted as though they had gotten a signal to grow. And every time they got a signal to grow, they responded by stopping their growth.

If they were right, the way to stop her cancer's growth could be to signal it to grow. And that was what a new melanoma drug — ipilimumab, its trade name Yervoy — was designed to do. It spurred the growth of normal T cells.

But if the researchers were wrong, the drug could kill her.

They spent two hours at a whiteboard on Wednesday, May 18, trying to understand what the fusion really meant. Then Dr. McDaniel took the data home and asked a colleague at Illumina to try to fish out a handful of crucial genetic sequences that were buried among 50 million others. On Sunday night, May 22, Dr. McDaniel had them and began trying to decipher them. By 10 p.m., he had it figured out. The TGen scientists' findings were real.

"The brake pedal had been wired to the accelerator," Dr. McDaniel said.

He worked all night, found a paper by scientists who had deliberately fused those very genes and discovered that, yes, the genetically altered T cells had their growth signals reversed.

At 5:45 a.m. Dr. McDaniel sent an e-mail to his collaborators.

"I was so tired at that point that, believe it or not, I had forgotten about the drug," he said.

He fell asleep and woke at 11 a.m., rushing back to his computer. The melanoma drug he had forgotten in his exhaustion should hit that target. And that could stop his mother's cancer from growing. "My jaw was just hanging open," Dr. McDaniel said. "The implications were so tantalizing that I didn't dare believe them."

#### A Remarkable Turnaround

Mrs. McDaniel had her first infusion on July 28, and the result seemed remarkable. Her oncologist, Dr. Gohmann, was overwhelmed. Her son, who had been terrified that he and the doctors might have made a terrible mistake, was overjoyed.

Mrs. McDaniel, who had not left her house for several months except to see her doctors, began going to movies and restaurants every day.

On Sept. 2, she and her husband went to the Heirloom Restaurant, in the middle of horse country, to celebrate their 50th wedding anniversary.

She had given away so many of her clothes when she thought she was dying that she puzzled over what to wear. She had a favorite blouse that was loosefitting and comfortable, but Mr. McDaniel recalled, "It was long gone." She could not drink wine with the medicines she was taking, so she and her husband sipped iced tea in the quiet dining room.

"We reminisced, but also talked about the future as we hoped it would be," Mr. McDaniel said.

But the reprieve lasted only weeks. By the end of September, the cancer was back.

Dr. McDaniel did not want to give up. Mrs. McDaniel's tumor was sequenced again, looking for a new mutation, but there was nothing striking. As Dr. McDaniel sifted through the data, he called his parents every day. They began calling him the governor, hoping he would bring his mother another stay of execution.

The doctors considered a less appealing target, a mutated gene that T cells use to stop growing. Unpublished studies in mice suggested that a kidney cancer drug might stop the growth of T cells with this mutation.

By then, Mrs. McDaniel's body was ravaged by the cancer and her treatments. She had entered hospice care, with a hospital bed in her home and a nurse and an assistant to help.

"We had this shaky evidence, based on the genome and on unpublished data," Dr. McDaniel said.

But the drug's side effects were mild, and her family and doctors decided she should try it.

"If we do nothing, she will be dead in one to six weeks," Dr. McDaniel explained.

Mrs. McDaniel took the drug on Nov. 26. But she was so ill that she was unable to get out of bed, unable to drink from a straw. Her son Tim took his children to her bedroom one at a time so they could say goodbye.

"She wasn't talking, but her eyes were open, and she acknowledged each one with a weak chuckle," Dr. McDaniel said.

Three days later, she briefly rallied. Her husband held her hand.

"She said, 'I love you,' " Mr. McDaniel said. "She then repeated it twice more. I kissed her forehead and told her that I loved her. Those were our last words to each other."

The next morning, Nov. 30, Mr. McDaniel woke early and went to his wife's room. Her breathing had become erratic. Worried, he stepped out and asked the hospice nurse to call the doctor. "In the seconds that I was absent, she died," Mr. McDaniel said.

The team that tried to save her was heartbroken too, and was left with a long list of what-ifs. "If you really look at it, what did we buy her?" Dr. de Castro asked. Mrs. McDaniel was dying last January. Yet would she have survived as long even without the sequencing or the drugs? Did the team make a difference?

"I hope we did," Dr. de Castro said, "but it's hard to know."

[Return to Top](#)

---

**States fight 'tourists' trafficking painkillers | [View Clip](#)**  
**07/08/2012**  
***Macomb Daily***

LEBANON, Ohio (AP) — As he sat in the doctor's office, ex-boxer and weightlifter Gerald Dixon explained that years of sports had left him in pain, especially his hands, and he was looking for relief.



After a cursory examination at the clinic in West Palm Beach, Fla., Dixon left with a prescription for 180 doses of OxyContin — and a plan to return to his Ohio home and sell them on the street.

The trips made by Dixon and others like him — authorities dub them “prescription” or “drug” tourists — have complicated the challenges investigators face trying to stem the flow of painkillers, whose prevalence have made drug overdoses the leading cause of accidental death in dozens of states including Ohio, Florida, Kentucky and Utah, surpassing car crashes.

Dixon, 52, a drug dealer for most of his adult life, had recently discovered a new angle on an old profession. By driving to Florida just once a month and acquiring a bagful of pain pills — legally and illegally — he could earn tens of thousands of dollars.

The only thing the medical clinics that Dixon visited in Florida cared about was the money, he said. A diagnosis for severe pain was easy to obtain.

“It’s all about cash, cash, cash,” Dixon said during a prison interview in April with The Associated Press. “You go, you pay the money, and they’re going to come back and say, ‘Yeah, you’re right, you was hurt.’”

Prescription tourists thwart local efforts to combat the illegal sale of painkillers and to treat addicts by bringing huge volumes of drugs in from outside. Cracking down on the trade also requires complicated prosecutions crossing multiple state lines.

These tourists are based in a variety of states, but investigators in Kentucky, Ohio and West Virginia — where authorities have already cracked down on local pill mills — are among the busiest trying to track trips to Florida, Georgia and elsewhere.

The lucrative business involves drug dealers dispatching underlings like Dixon to states with numerous pill mills where they load up on painkillers, then return to sell the drugs to addicts willing to pay as much as \$100 a pill, or as much as 10 times the drugstore price.

Florida for years was a popular destination because of its virtually unregulated pain clinic industry, which provided easy access to thousands of painkillers marketed under names like OxyContin, Vicodin and Percocet.

As Florida cracks down on its pill mills, the clinics have migrated to states like Georgia, which had practically none three years ago and now has as many as 150, said Richard Allen, director of the Georgia Drugs and Narcotics Agency.

Runners — another term for people like Dixon or addicts sent to buy pills and take them home — are coming from as close as Kentucky and Tennessee and as far away as Arizona and Nebraska, Allen said.

“They’re like a swarm of locusts,” he said. “Once they have a scrip, they’ll hit every pharmacy in the state trying to get them filled.”

In eastern Kentucky, several residents arrested in 2009 in a massive drug sweep had visited the Lauderhill Medical Clinic in Oakland Park, Fla. U.S. Attorney Kerry Harvey estimates that nine of every 10 patients at the clinic are from Kentucky. He prosecutes about five dozen cases a year involving prescription drugs.



At West Virginia's Huntington Tri-State Airport, authorities have dubbed low-cost flights to Florida aboard Allegiant Air the OxyExpress. The airline isn't accused of wrongdoing, and spokeswoman Jessica Wheeler says it hasn't been approached by authorities.

In Tennessee, strict laws governing pain clinics force drug dealers out of state for supplies, using Interstate 75 to bring pills back from Florida or move them farther north, said Kristin Helm, spokeswoman for the Tennessee Bureau of Investigation.

Ohio has prosecuted several prescription tourists in recent months, with a federal judge in December sentencing Christopher Thompson of suburban Columbus to 15 years in prison for leading a scheme involving more than a dozen other people who traveled from Ohio to Florida, obtained and filled prescriptions for oxycodone and other drugs, and mailed the pills back to central Ohio for illegal distribution.

"The effect is the same effect as if they were coming out of our own pain clinics," said Aaron Haslam, who directs Ohio's anti-painkiller abuse efforts in the state's attorney general's office. "We have overdoses all over the state of Ohio because of it."

Defendants in one southern Ohio case brought back drugs worth \$50,000 on the street in one trip, Haslam said.

Authorities have fought back with extensive crackdowns in Florida against pill mills and with prosecutions in states like Kentucky, Ohio and West Virginia of both drug tourists and the Florida doctors who wrote prescriptions. State medical boards also regularly discipline or revoke the licenses of doctors who overprescribe painkillers.

Florida is finally seeing a drop in pill mills and doctors prescribing painkillers after enacting a 2011 law toughening penalties against doctors and clinics engaged in prescription drug trafficking.

Still, such a stance has consequences. A group sued the state in 2010 over the pill mill crackdown. One of the doctors, Paul Sloan, owner of Florida pain management clinics in Fort Myers and Sarasota, says that there's no question that some doctors and clinic owners were doing bad things, but that the state has overreacted.

"We're dealing with a war on legitimate medications that's being dealt with like we're all cartels and drug lords," he said.

Doctors in that lawsuit defended disbursing prescriptions to patients who paid cash, saying uninsured patients with chronic pain relied on pain pills for relief because they often couldn't afford more expensive procedures or services.

Posing as such a patient can serve a prescription tourist well.

Dixon said he traveled to West Palm Beach for about seven months in 2008, visiting clinics and picking up prescriptions and pills over a two or three-day period. Dixon never visited more than one doctor, but soon was also buying pills from people he met on the streets in deals arranged in motels.

"Once you get to motels down there, it's just like a Wal-Mart or Kmart or Kroger store for drugs, pills, whatever," Dixon said. "Once you get in that clique, they will find you."

He said it was not uncommon to see pills offered from bulging 50-pound dog food bags filled

with the prescriptions.

Dixon was arrested in 2008 returning from what would turn out to be his last trip, set up, he says, by a fellow drug dealer. He had 6,000 pills hidden in a false exhaust system he'd installed beneath the car. He is serving a four-year sentence for drug trafficking charges. Although painkillers are a legal drug, it's against the law for anyone but a doctor or pharmacist to dispense them.

Crackdowns like Florida's may be driving prescription tourists to states like Georgia, Haslam said.

"We're squeezing a balloon," he said. "And as you squeeze the balloon, the air in the balloon goes someplace else."

---

Andrew Welsh-Huggins can be reached at <http://twitter.com/awhcolumbus>

[Return to Top](#)

---

**Workplace clinics gaining favor among employers | [View Clip](#)**

**07/08/2012**

***Chicago Tribune - Online***

As employers look for ways to control health-care costs, some are opening their own work-site health clinics.

Such on-site health services are slowly catching on in Ohio. Officials with Cleveland-based CBIZ, which consults with businesses on benefits and health insurance, said they have seen requests for feasibility studies in Ohio double so far this year compared with the first half of 2011.

"We're at a tipping point, I believe, of a lot of employers going this way," said Polly Thomas, CBIZ's on-site clinic consulting director.

Employers traditionally offered services relating to occupational health, said Helen Darling, president and CEO of the National Business Group on Health. What's different now, she said, is that employers are creating health services for non-occupational health reasons. A National Business Group on Health survey of employers last year found that 37 percent of survey respondents currently offer on-site health clinics at one or more sites, while 16 percent are considering such clinics.

In some cases, Darling said, employers are offering preventative care and screenings; in others, employers are trying to reach groups of workers who don't regularly go to the doctor, such as middle-aged men.

The city of Westerville is considering setting up a centrally located clinic in conjunction with Otterbein University, the local library, the Chamber of Commerce and Westerville City Schools. The city has seen an average 9 percent increase in its health-care costs in each of the past four years, a spokeswoman said. The city pays about \$4.5 million a year for health care, or nearly 3 percent of its budget.

Columbus-based research giant Battelle said it has three doctors and two nurse practitioners on staff, primarily for occupational health services, such as medical monitoring for exposure to biological or chemical substances. But Battelle has "seriously explored" providing primary-care services to workers, a spokeswoman said. No final decision has been made.

Businesses see the services as a way to cut down on everything from pricey visits to emergency rooms to employee absenteeism. While such services are more common at larger employers such as American Express and Walt Disney World, even employers with a few hundred workers might be able to justify such services, Thomas said.

Businesses don't have to employ a physician or nurse practitioner to offer on-site clinic services. Most outsource those services to a third party, she said. While the concept makes sense for many companies, a literature review published in April in the Journal of Occupational and Environmental Medicine found there's a "remarkable lack of information" on whether work-site clinics pay for themselves. The review also noted that such clinics, while providing cost-effective services, carries a risk of fragmenting care delivery and increasing overall health-care costs.

Some larger local businesses already offer work-site services. Cardinal Health in 2009 opened an on-site wellness center, which includes primary care, physical therapy, preventative health screenings and a pharmacy.

Worthington Industries is a local pioneer in providing such services in-house, offering them since 1995. Its on-site health clinic and pharmacy reduced its health-care costs by 4 percent in 2011, a company spokeswoman said. The health clinic has about 8,500 patient visits annually, while its pharmacy each year fills 35,000 prescriptions, 15,000 of which are mailed to employees outside central Ohio. A big part of those savings are achieved by filling prescriptions with generic instead of brand-name drugs, a company spokeswoman said.

Worthington Industries provides a range of primary-care services around the clock, as well as wellness programs.

While many physician offices have time only to treat the illness at hand instead of looking at broader health issues, "We have the time to focus on those preventative issues to keep people at low and moderate risks (of chronic disease) from progressing to a higher risk," said Dr. Bill Gegas, Worthington Industries' medical director.

It all makes for a more educated, health-conscious employee, said Gegas, who sees patients part-time at the clinic.

CBIZ's Thomas said employers have to make their clinics part of a larger wellness strategy and can't assume employees will automatically use them.

Offering on-site health clinics also requires a long-term commitment, Thomas said. She typically recommends that businesses don't offer an on-site clinic if they won't realize savings in the first year; thereafter, savings can be harder to come by.

[bsutherly@dispatch.com](mailto:bsutherly@dispatch.com)

@BenSutherly

[Return to Top](#)

---

**Canada: Province boosts pharmacists' compensation | [View Clip](#)**

**07/07/2012**

***St. Albert & Sturgeon Gazette - Online***

Pharmacists across the province will have a little extra pad to their pocket as a result of new government compensation.

Funds will now be paid to pharmacists for performing each of the seven publicly-funded health services, like prescription renewal and medication injections.

"The ability for pharmacists to provide this service is not new. What is new is that pharmacists will now be compensated for delivering those services," said Neil Cameron, president of the Alberta Pharmacists' Association.

Beginning July 1, pharmacists can bill for altering prescriptions, authorizing medication in a medical emergency, creating a Comprehensive Annual Care Plan (CACP), creating a Standard Medication Management Assessment, and, if they have prescribing authority, prescribing medication.

"There's anxiety whenever there is change but the general feeling of pharmacists is it's a relief that we're actually finally being paid for what our scope of practice has enabled us to do," Cameron said.

Pharmacists have been able to provide the services since 2007 when changes to government legislation were enacted, and have since provided the services without compensation.

Pharmacists will now be compensated \$20 for prescription renewal or adaptation and medication injections, while pharmacists with prescribing authority receive \$25.

Creating an annual care plan will put \$100 in a pharmacist's pocket, with an additional \$25 going to pharmacists with prescribing authority.

Sara Karlstrom, pharmacist at Health Select Pharmacy in Tudor Glen Market, said the ability to bill the government for the services will bring in more money for pharmacies and pharmacists, but will also benefit patients.

"Not all patients have doctors that have time to sit down with them for 20 minutes and go through all their medications with them once a year," she said.

She said pharmacists perform these services on a daily basis. She is pleased they will now receive compensation.

Cameron said it is too early to predict how much additional pay pharmacists can expect to see on their paycheques.

Fred Horne, minister of Health and Wellness, said the new pharmacy services are meant to "complement" the services offered by a physician.

"Pharmacists and doctors each bring a different specialty to health care, so making better use of a pharmacist's specialty also makes better use of both the doctor's and patient's time," he said.

Karlstrom agreed, adding it is important for patients to be aware of the different services offered by pharmacists and physicians.

"We still get patients come in thinking that we're replacing their doctors, which is inaccurate," she said. "We're just here to bridge the gap that exists sometimes when patients can't get in to see their family physicians."

Horne said the implementation of the Pharmacy Services Framework will decrease waiting lists for physicians, enabling patients to have more timely access to public health care.

"We have a lot of demands in our health-care system and we have an obligation to use every profession to their full scope of training and expertise," Horne said.

The cost of the program will be funded solely from government savings from the cost of generic drugs.

Effective July 1, the amount the Alberta government spends on generic drugs has decreased 10 per cent. It used to pay 45 per cent of the name-brand cost, but now pays 35 per cent - a cost now on par with neighbouring provinces.

This reduction in generic drug costs is expected to save \$85 million annually.

NOTE: To post a comment in the new commenting system you must have an account with at least one of the following services: Disqus, Facebook, Twitter, Yahoo, OpenID. You may then login using your account credentials for that service. If you do not already have an account you may register a new profile with Disqus by first clicking the "Post as" button and then the link: "Don't have one? Register a new profile".

The St. Albert Gazette welcomes your opinions and comments. We do not allow personal attacks, offensive language or unsubstantiated allegations. We reserve the right to delete comments deemed inappropriate. We reserve the right to close the comments thread for stories that are deemed especially sensitive. For further information, please contact the editor or publisher.

blog comments powered by Disqus

[Return to Top](#)

---

**Half of all heart patients make medication errors | [View Clip](#)**  
**07/07/2012**  
**MSNBC.com**

NEW YORK (Reuters Health) - Half of all heart patients made at least one medication-related mistake after leaving the hospital, and guidance from a pharmacist didn't seem to reduce those errors, in a new study.

Consequences of mistakes - such as forgetting to take certain drugs or taking the wrong dose - can range from side effects like constipation to more serious drops in blood pressure. Two percent of errors were life-threatening.

Hospitals involved in the study were already taking steps to prevent medication mistakes in addition to the extra pharmacist intervention, said Dr. Sunil Kripalani, the study's lead author

from the Vanderbilt University Medical Center in Nashville, Tennessee.

"We were surprised to see that in spite of these efforts that 50 percent (of patients) were still having these medication errors," he told Reuters Health.

Although the pharmacist visits didn't help the average patient, he added, certain ones seemed to benefit - such as patients who were on multiple drugs or had trouble understanding health information.

As for traditionally lower-risk patients, he said other strategies to prevent errors may be needed.

#### ONE-ON-ONE MEETINGS

For their study, Kripalani and his fellow researchers followed patients who had been hospitalized for heart conditions at Vanderbilt University Hospital and Brigham and Women's Hospital in Boston.

Half of the patients were randomly assigned to attend two visits with a pharmacist, who looked at which medications patients were taking and instructed them on what to do once they left the hospital to manage their prescriptions and reduce side effects.

The patients also received tools, such as a medication chart and pillbox, to use at home.

After leaving the hospital, the patients received a phone call within a few days from one of the study's coordinators who was able to identify medication-related problems over the phone. If any were found, a pharmacist made a follow-up call.

The other heart patients did not receive any special treatment outside of normal hospital procedure, which is for a nurse or doctor to spend a few minutes with patients before they leave the hospital to discuss their medications.

One month later, 432 out of the 851 patients had made at least one harmful or potentially-harmful medication error, including missing doses, taking the incorrect dose, stopping a drug too early or continuing it for too long.

Just under one-quarter of those errors were judged to be serious and about two percent were life-threatening. And there was no difference in the number of errors made by patients who did or didn't get extra pharmacist advice.

One limitation, the researchers note in their Annals of Internal Medicine report, is that not all patients in the intervention group had two pharmacist visits or a follow-up call as intended. It's also unclear whether the findings would apply to patients being treated for other, non-heart conditions.

#### KEEP A LIST

Kevin Boesen, director of the Medication Management Center at the University of Arizona College of Pharmacy in Tucson, told Reuters Health he's not surprised that many people are confused after leaving the hospital.

"To me, I think (the finding) highlights the challenge for the transition from hospital to home," he said.

Boesen added that it's important for patients to meet with their regular pharmacist and primary care doctor after they get out of the hospital or fill a prescription somewhere else.

"I think there is the assumption that when a patient goes to a pharmacy the pharmacist will have a list of all the medication they're on," he said. But that's not always the case.

A key safety step patients can take, Boesen and Kripalani agreed, is to keep track of all of the drugs they're taking and carry a list.

"The single most important thing patients and families can do to promote safety with their medications is to always keep a medication list with them," Kripalani said. That list should include drug doses and patients' reason for taking each medication, he added.

"If a patient simply carries that medication list, so everyone is working off of one list, that definitely helps," said Boesen.

SOURCE: <http://bit.ly/P65Kp7> Annals of Internal Medicine, online July 2, 2012.

[Return to Top](#)

---

**Canada: Ont Health Minister moves to block generic OxyContin | [View Clip](#)**  
**07/07/2012**  
**CFRB-AM - Online**

Ontario is urging Ottawa to block generic brands of OxyContin from the Canadian market.

When Purdue Pharmaceuticals' patent runs out this fall, other companies will be able to start making generic versions of the drug.

The Globe and Mail reports Ontario's Health Minister wants Health Canada to reject applications for those generic versions.

Deb Matthews says allowing copies of the drug will only lead to more addiction & death.

[Return to Top](#)

---

**After Delay, OxyContin's Use in Young Under Study | [View Clip](#)**  
**07/07/2012**  
**New York Times, The**

To learn how best to prescribe powerful drugs to children, Congress passed a law in the 1990s that rewarded drug makers for conducting clinical studies involving children. Among the incentives for cooperating companies was a possible six-month extension of protection from generic competition after a drug's patent expired.

More than a decade ago, federal regulators asked the producer of OxyContin, a widely abused narcotic painkiller, to run such a trial under the law. The producer, Purdue Pharma, started a study of children but dropped it in 2004, citing limited financial resources. Now, with OxyContin's patent set to expire in 2013, the company has begun another study of young



patients -- opening the possibility for a patent extension for Purdue, worth hundreds of millions of dollars.

The company's long delay in complying with the Food and Drug Administration's request rankles critics, who say it is coming far too late for many children. Since the time that the F.D.A. asked Purdue to conduct the research, doctors have prescribed OxyContin to tens of thousands of children and teenagers without the benefit of study data to guide them.

"It looks to me like a raw, crass, last-gasp exploitation of a drug that has been synonymous with misuse, abuse and harm to patients," said Dr. Arthur Caplan, the head of the division of medical ethics at NYU Langone Medical Center.

A spokesman for Purdue, which is based in Stamford, Conn., said that the company decided in 2004 to redirect the money it was spending on a pediatric trial into an effort to develop a version of OxyContin that was more resistant to being abused.

"We reinitiated the remaining pediatric trials once we had the necessary resources to continue them," said that spokesman, James W. Heins. "These trials are challenging to conduct and can take years to complete."

In 2004, the year Purdue Pharma abandoned the trial, sales of OxyContin reached \$1.7 billion, according to IMS Health, a consulting firm. Over the last decade, sales of the painkiller have exceeded \$15 billion.

No one questions that OxyContin, a time-release version of a narcotic drug or "opioid" called oxycodone, can benefit some younger patients suffering severe pain from cancer or conditions like sickle cell anemia. Some experts say the study will provide useful data to guide the drug's use.

But other experts worry that little is known about OxyContin's long-term risks in adults, much less children.

For example, opioids like OxyContin have been shown to reduce the production of sexual hormones in both men and women, leading to extreme lethargy and lack of drive.

"Opioids have endocrinological effects and therefore potential developmental complications are a concern," said Dr. C. Richard Chapman, the former head of the Pain Research Center at the University of Utah. "It just doesn't make sense."

In 1997, Congress passed the Best Pharmaceuticals for Children Act, the statute that created the incentive for drug makers to test the products in young patients. Not long after the bill's passage, the Food and Drug Administration formally requested that Purdue Pharma conduct three studies of oxycodone, OxyContin's active ingredient, said the company spokesman, Mr. Heins.

In written responses to questions, Mr. Heins said that the company completed two of those studies, both of which involved oxycodone in liquid form, the way a drug might be administered in a hospital using an injection or through an intravenous drip. But the third study requested by the F.D.A. -- a pediatric trial of OxyContin itself, a time-release pill form of oxycodone -- was not conducted.

Mr. Heins said the company abandoned the trial in 2004 after enrolling just a few patients. "It had to be discontinued because of a lack of resources," Mr. Heins wrote.



Mr. Heins added the company focused its spending on the development of a more abuse-resistant form of OxyContin. Purdue Pharma has since patented that version of the drug and is now marketing it.

Pediatric drug studies can cost millions of dollars to conduct.

A spokeswoman for the F.D.A., Karen Riley, declined as a matter of policy to discuss the agency's interactions with Purdue Pharma because it involved business confidential information.

In 2009, about a decade after the F.D.A.'s original request, Purdue Pharma assembled a panel of experts to discuss how to best proceed with the pediatric trial of OxyContin, Mr. Heins said. New talks with the F.D.A. followed and an agreement was reached in 2010 on a trial design, he added.

The company's pediatric study drew public attention this week when The Daily, an online publication, wrote an article about it.

Dr. Nathaniel P. Katz, a pain management expert, said that over the last decade, the F.D.A. had changed the type of information it seeks from makers of narcotic painkillers who run pediatric trials. Initially, he said, the agency wanted studies similar to traditional trials in which some patients were put on the drug being studied and other patients received a placebo like a sugar pill.

"Where are you going to find parents willing to take the risk that their child will be put on a placebo?" Dr. Katz said.

The study that Purdue Pharma is currently conducting is not a placebo trial. Instead, it involves about 150 patients from 6 to 16 years of age who are already on opioid painkillers. In the study, which is expected to be completed next year, those patients will get OxyContin for up to six months.

Senator Richard Blumenthal, a Democrat of Connecticut who investigated Purdue Pharma while attorney general of that state, said that while the company might benefit from the pediatric testing law, its delay in running the OxyContin trial did not appear to reflect the statute's spirit.

"If a drug is going to be used on children, tests to ascertain its safety should be run as early as possible," he said.

PHOTO: Purdue Pharma, OxyContin's maker, is conducting a trial of 150 patients from 6 to 16 years of age on opioid painkillers. (PHOTOGRAPH BY DARREN MCCOLLESTER/GETTY IMAGES) (B6)

Copyright © 2012 The New York Times Company

[Return to Top](#)

---

**Express Scripts, Walgreen Flap Opens Door for 'Narrow Networks' | [View Clip](#)**  
**07/09/2012**

***Dow Jones Newswires***

The strained relationship between Express Scripts Holding Co. (ESRX) and Walgreen Co. (WAG) has heightened interest in networks that limit the number of drugstores available to pharmacy-benefit customers, but can result in savings for their employers and health plans.

The aim of so-called "narrow networks" is to strike a balance between drugstore options and prices for health-plan sponsors. Because Express Scripts' members saw limited disruption when nearly 8,000 Walgreen drugstores left the pharmacy-benefit manager's network, other pharmacy-benefit customers are exploring plans to trade some retail convenience for savings, according to industry observers.

This poses risks for Walgreen because Express Scripts is pitching networks that don't include the nation's biggest drugstore chain to clients of Medco Health Solutions, according to consultants. Express Scripts bought Medco in April to create the largest pharmacy-benefit manager, or PBM. Express Scripts members have had to use other pharmacies since Jan. 1, but Medco members generally still have access to Walgreen outlets.

These narrow networks are "something that's getting a lot more focus and attention than in prior years," said Larry Merlo, chief executive of CVS Caremark Corp. (CVS), which has both the second-largest PBM and pharmacy chain in the U.S.

PBMs handle drug benefits for health plans and corporate clients and strike deals with pharmacies over prescription reimbursement rates. Speaking at a recent conference, Mr. Merlo credited Express Scripts with helping members smoothly transition to new pharmacies--CVS has reaped significant rewards as Walgreen's biggest competitor--while showing limited pharmacy networks can be beneficial rather than disruptive.

These arrangements generally involve a smaller number of pharmacies where PBM members can get coverage for their medicine. The pharmacies within that network offer better rates in return for more traffic, creating savings for health plans and companies hiring PBMs.

Shifts to these networks won't happen overnight, and a busy PBM selling season is ongoing, but "it's more of a discussion point than it's been in the past," said David Dross, who leads the managed-pharmacy practice at consulting firm Mercer LLC. Tony Perkins, senior director of investor relations at PBM SXC Health Solutions Corp. (SXC), cited a "huge spike" in requests to explore narrow networks, driven by the need to create comparisons with Express Scripts offerings, but a smaller increase so far actually using such plans.

For big pharmacy chains, giving up some pharmacy profits to get in narrow networks can mean more traffic in the retail aisles. But pressure to cut prices and join these networks creates challenges for the nation's independent, community pharmacies, which typically get at least 90% of their revenue from prescriptions, said Douglas Hoey, chief executive of the National Community Pharmacists Association trade group.

These community pharmacies represent more than one-third of the roughly 60,000 drugstores in the U.S. Mr. Hoey noted that small pharmacies often serve towns that don't have many other options, making them important locations.

Nevertheless, the vast U.S. retail pharmacy industry creates room for PBM customers to whittle down network sizes, said Edward Kaplan, a consultant for PBM clients who leads the managed-pharmacy practice at the Segal Co. Express Scripts' mostly uneventful transition away from Walgreen has served as important evidence as clients weigh modest savings against potential disruptions, Mr. Kaplan said.

This evidence could have further implications for the Express Scripts/Walgreen's relationship. The two companies have declined to say when the contract between Walgreen and Medco is scheduled to end, but industry consultants say Express Scripts is offering Medco clients the opportunity to carve out Walgreen in return for savings. Some Medco clients have taken Express Scripts up on the offer, according to Robert Ferraro, a pharmacy-benefits specialist who works with PBM clients at Xerox Corp.'s (XRX) Buck Consultants.

Walgreen on Thursday reported a 15% drop in June same-store pharmacy sales, the latest evidence of businesses losses linked to the Express Scripts dispute. Walgreen declined to discuss the Medco matter beyond recent comments on conference call, where Chief Financial Officer Wade Miquelon said Medco clients want to keep Walgreen, and that there was "very little risk" in losing that business.

Express Scripts confirmed it's actively marketing narrow networks to clients, though it wouldn't discuss specifics or its Walgreen strategy.

"We are out there showing every client the value that a narrow network" brings, said Tim Wentworth, a senior vice president overseeing sales and account management at Express Scripts, who joined the firm from Medco. That "certainly includes legacy Medco clients," he said.

[Return to Top](#)

---

**Delaware: Return of the independent druggist | [View Clip](#)**

**07/08/2012**

***News Journal - Online***

When the Happy Harry's drugstore chain was swallowed up by Walgreens in 2006, it marked the end of an era for thousands of Delawareans.

It also seems to have begun a time of opportunity for independent pharmacists.

The national chains have come to dominate Delaware after the Happy Harry's deal, but a growing number of entrepreneurial pharmacists are opening their own small stores around the state, hoping to snag market share through a tighter focus on customer service, and less of an emphasis on non-medical sales.

Chains offer everything from candy bars to cat food, but the community pharmacies stick to the prescriptions and other health care products that once were the industry's bread-and-butter. With chain pharmacists sometimes too busy to step out from behind the counter and deal with questions, the independent owner-operators are working to set themselves apart by building relationships with customers.

It's that personal attention that seemed to fade in Delaware when Happy Harry's disappeared and the national chains took over, customers say.

"They've diversified too far, the wrong way," said James Wake, who with wife, Priya Bhatia, are regular customers at First State Pharmacy in Brandywine Hundred, opened a year ago by pharmacist Chas McCormick.

"What I was trying to do was kind of get back to that Happy Harry's neighborhood pharmacy

culture that we all grew up with in Delaware. I thought that was missing,” said McCormick, himself a former Happy Harry’s pharmacist.

At the same time, with the chain stores offering nationwide networks and multi-state locations, the community pharmacies face challenges in their quest to remain competitive.

“I think there is clearly a plus and clearly a negative,” said independent pharmacy customer Peter McCarthy of Brandywine Hundred, who noted that he’s left without many options when traveling.

The independents also have far more ground to make up in Delaware, where they still represent a relatively minor part of the market.

Nationally, independent pharmacies represent 40 percent of the sector, said John Norton, spokesman for the National Community Pharmacists Association. In Delaware, there are 117 chain pharmacies, and just 19 independents – about 14 percent of the market.

[Return to Top](#)

